DEPARTMENT OF HEALTH SERVICES

714 / 744 P STREET P.O. BOX 942732 SACRAMENTO, CA 94234-7320 (916) 654-0499

March 30, 1999



N.L.: 04-0399 Index: Benefits

Supersedes N.L. 38-1292

TO: County California Children Services (CCS) Administrators and Medical

Consultants, Genetically Handicapped Persons Program (GHPP) and State

Children's Medical Services (CMS) Regional Offices Staff

SUBJECT: NUTRITION PRODUCTS AS A CCS/GHPP BENEFIT

I. BACKGROUND

This letter supersedes and replaces Numbered Letter (NL) 38-1292, Nutrition Products. This letter revises the criteria for authorizing nutrition products and details the documentation needed when nutrition products and special formulas or additives are requested as benefits.

II. POLICY GUIDELINES

Parenteral solutions, replacement formulas or products, calorie dense formulas or products, and additives are CCS benefits on an outpatient basis when required as part of the medical management of a CCS-eligible condition. Each product category and criteria for authorization are discussed below.

A. Parenteral Solutions:

Parenteral solutions provide nutrition support for individuals with conditions which preclude or limit the use of the gastrointestinal tract. Two methods of administration of parenteral nutrition are available: Total Parenteral Nutrition (TPN), which is nutrition support delivered through a central line, and Peripheral Parenteral Nutrition (PPN), which is nutrition support delivered through a peripheral vein. Indications for parenteral nutrition support may include impaired gastrointestinal function, extraordinary caloric demand, and/or a need to rest the bowel. Due to the risk of this method of feeding, parenteral nutrition is reserved for severely ill individuals.

Parenteral solutions (TPN and PPN) are benefits for a patient with a CCS-eligible condition when the nutritional need cannot be met solely by other enteral routes (e.g., oral, nasogastric, gastrostomy feedings, etc.).

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B. Replacement Products:

Replacement products are formulas (or products substituting for the formulas, e.g., bars), specifically designed to replace nutrient component(s) that, because of an underlying CCS-eligible condition, cannot be tolerated. The types of replacement products are discussed below.

1. Special Purpose Replacements:

Special purpose replacements are designed for individuals with inborn errors of metabolism or specific organ dysfunction (e.g., renal, cardiac, or liver disease) who require a special product as an integral part of the medical management of the disorder. It is not known when such a replacement can be safely terminated, probably not until the organ dysfunction is resolved. Special purpose replacements do <u>NOT</u> include medical foods such as low protein bread and pasta products. The criteria for those products are covered in CCS N.L 05-0399.

The following list are groups of replacement products that illustrate the use of special purpose replacements for CCS-eligible conditions with examples of specific products.

- a. Amino acid-restricted diets for patients with inborn errors of metabolism such as Phenylketonuria (PKU), Hemocystinuria, or Maple Syrup Urine Disease (examples: Profree, Lofenalac, Phenyl-Free, Maxamaid, PKU1, PKU2, PKU3, MSUD1, OS1, HMO1, Product 3200).
- b. Carbohydrate-restricted diets (galactose, lactose, sucrose, fructose- free diets) for patients with Glycogen Storage Disease, Ketogenic Diet, or Galactosemia (examples: CHO Free, Lacto free, Criticare, Vivonex.
- c. Low electrolyte formula for CCS-eligible clients with renal or cardiac conditions with hyperphosphatemia or hypernatremia (examples: Sim 60/40 and Calcilo).
- d. High mineral, specialized formula for preterm infants with a CCS-eligible condition such as BPD or short bowel syndrome (examples: Enfamil 22, Neocare).

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2. <u>Elemental Replacements:</u>

Elemental replacements are formulas designed for individuals who have a dysfunctional gastrointestinal tract and are unable to tolerate and absorb a complete formula composed of whole proteins, fats, and carbohydrates. These formulas are specifically prepared from basic elements (e.g., glucose polymers, peptides, amino acids, essential fatty acids, medium chain triglycerides, etc.) to create an easily absorbed formula.

An elemental replacement formula is a benefit for a patient who has malabsorption or short bowel syndrome secondary to a CCS-eligible condition such as NEC, gastroschisis, ulcerative colitis, HIV infection, etc. The duration of the treatment with an elemental replacement is variable and determined by the absence of the symptoms when the patient is placed on a non-elemental formula or is able to tolerate regular foods.

Examples of elemental formulas include, but are <u>not</u> limited to such products as Criticare HN, Tolerex, Pediatric Vivonex, Neocate, Vital HN, Peptamen, Peptamen Jr., Pregestimil, and Nutramigen.

C. Calorie Dense Enteral Products:

Calorie dense enteral products include formulas or products substituting for the formulas (e.g., bars) that provide a caloric density such as one calorie per cc or greater or 30 calories/ounce or greater. Examples include, but are <u>not</u> limited to Ensure, Ensure Plus, Pediasure, Sustacal, Sustacal with Fiber, Isocal,-Jevity, Kindercal, TwoCal HN, Boost, Boost Plus, Scandishake.

Calorie dense enteral products are prescribed for individuals with fluid restrictions or nutritional deficiencies related to growth, specific biological indices associated with severe, debilitating conditions, or specific feeding intolerances. These products may be administered orally or through a tube. They may provide supplemental calories or provide the sole source of nutrition.

Calorie dense enteral products are a CCS benefit when the product is required as part of the medical management of a CCS-eligible condition being provided on an outpatient basis and the one or more of following criteria are met:

1. The child has a nutritional or growth deficiency, as defined by the parameters below, and there is a documented inability to correct the deficiency using other foods such as home-prepared calorie dense foods. The nutritional or growth deficiency may be a direct result of the

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debilitating CCS/GHPP-eligible condition (e.g., HIV infection or, Cerebral Palsy); be caused by an infection, malignancy (e.g., cancer) or depletion of nutrient stores due to malabsorption (e.g., G.I.), dialysis, vomiting, etc; or secondary to a condition with increased caloric needs. The presence of a feeding tube (nasogastric, gastrostomy, etc.) in the absence of the above criteria is not sufficient for authorization of calorie dense enteral formulas as a CCS benefit.

Nutritional or growth deficiencies are defined as:

- a. For infants and children, weight loss or inability to maintain a normal rate of weight gain or increase in height for age (as defined by growth velocity curve or National Centers for Health Statistics (NCHS) pediatric growth charts) in a prepubertal child after a documented increased intake of regular foods;
- b. Low birth weight (LBW) or very low birth weight (VLBW) infants up to 24 months of age who are not able to maintain a normal rate of weight gain or are below the fifth percentile, weight for age, on the VLBW growth charts;
- c. Infants or children to 18 years who have an inability to maintain weight for length or weight for height above the fifth percentile (on the NCHS pediatric growth chart or the referenced table) while consuming regular foods.
- d. Individuals (used primarily in individuals who have reached their maximum growth potential, usually 18 years or older) who have an inability to maintain a Body Mass Index (BMI) greater than or equal to 19.
- 2. The inability to consume by mouth greater than 80 percent of the Recommended Dietary Allowance or calculated daily needs for calories and/or protein;
- 3. Children with decreased linear growth velocity;
- 4. Serum albumin less than 3.5 gm/dl;
- 5. Triceps skin-fold thickness less than the tenth percentile for age;
- 6. A CCS-eligible medical condition that causes oral feeding difficulties resulting in:

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- a. prolonged feeding times (more than 30 minutes per feeding to achieve adequate caloric intake); or
- b. risk of aspiration; or
- c. swallowing/choking problems with solid textures.

D. Additives:

Additives are modular products or non-whole food preparations that may be added to regular foods or formulas in order to provide supplemental calories/nutrients, or to increase the absorption of the foods or formulas. Examples of additives include, but are <u>not</u> limited to, carbohydrate supplements such as Polycose, fat supplements such as MCT Oil or Microlipid, protein supplements such as Casec or ProMod, and products to thicken liquids to increase caloric consumption such as Thick-it or Thicken Up.

III POLICY IMPLEMENTATION

- A. Prior authorization is required for the provision of nutrition products. The determination of medical necessity for a nutrition product is the responsibility of the CCS/GHPP medical consultant. This responsibility may be shared with or delegated to the CCS/GHPP program nurse consultant or nutrition consultant.
- B. CCS requests for nutrition products shall be submitted by the provider to the County CCS office. GHPP requests shall be submitted to the GHPP office.
- C. For initial and subsequent requests for extension, a "Request for CCS Nutritional Formula and Equipment" or "Request for Calorie Dense Formulas" form must be completed and include the following medical justification:
 - 1. Prescription signed by CCS-authorized center physician;
 - 2. Anthropometric data including plotted NCHS growth charts, LBW/VLBW growth charts, or BMI;
 - 3. Special Care Center registered dietitian's nutritional assessment;
 - 4. Special Care Center physician medical reports/records.

The attached documentation must be current, that is within six months of the requests for CCS or within one year of the requests for GHPP.

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- D. When requests are for an extension of an authorization, a report of periodic reevaluation of the need and effectiveness of the nutrition product by the CCSauthorized center physician and nutritionist must be submitted with requests for extension.
- E. Nutrition products shall only be authorized for outpatient use and for a specified quantity and period of time, not to exceed six months.
- F. Authorizations are to be issued only to a pharmacy.
- G. More than one nutritional product may be authorized at the same time if they are medically necessary, not redundant, and not in excess of required calories, proteins or other nutrients.
- H. When calorie dense product requests are denied or deferred for required documentation, and the individual appears to be at risk for failure-to-thrive or malnutrition, GHPP staff or county CCS case managers shall contact the center staff (social worker, dietitian, or nurse) for follow-up.

If you have questions regarding this policy letter, please contact your CMS Regional Office Nurse Consultant or the GHPP Nurse Consultant.

Maridee A. Gregory, M.D., Chief Children's Medical Services Branch

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Enclosure

REQUEST FOR CALIFORNIA CHILDREN SERVICES (CCS) NUTRITION PRODUCTS AND EQUIPMENT

DIRECTIONS: This request must be signed by a CCS-outhorized center physician. For children less than 18 years old, a National Center for Health Statistics pediatric growth chart is to be plotted with serial measurements and submitted with this form. Medical justification I required. This request and its approval will be limited to six months. A request for an extension must be submitted using the same om prior to the end of the authorization period. Patient Name:_____ _____ ccs #:___ Center: ______ Location:____ Medical Dx:_____ Weight:_____ Height:____ Nutrition Goal:____ NUTRITION PRODUCT: [] Enteral: [] P.O. [] Enteral Tube (specify type)_____ [] Parenteral: [] JPN [] PPN [] Premixed Product Name:___ Quantity per 24 Hours:_____ Expected Duration (if less than 6 months):_____ JUSTIFICATION: QUIPMENT: [] Pump: Type and Brand______ [] IV Pole SUPPLIES: [] Feeding Sets [] Other, specify_____ [] Central Line Supplies (attach list) Specify Quantity per Month:_____ VENDOR Name:______ Telephone #:_____ Address:____ Zip Code Street City JUSTIFICATION:____ The information on this form is being treated as a physician prescription for medical care and services, and therefore, MUST be signed by the treating physician. Name:___ _____ License No.:_____ Signature: ______ Telephone No.:_____

REQUEST FOR CALORIC DENSE FORMULA California Children's Services (CCS) and Genetically Handicapped Persons Program (GHPP) Patient Name: CCS Number: CCS Center: Hospital: Medical Diagnosis: Nutrition Product Requested: (Name & Company) Calorie per ounce: (over 30 (?) kcal/ounce) Prescribed no. ounces/day (24 hours): Daily caloric requirement: Calories from dietary intake: % Expected duration of use of formula (if less than 6 months): Justification of Medical Need DOB Sex. Age Date of visit: Height. %tile Weight %tile BMI (adults or teens Percentile wt/ht: only): Date of visit: Height %tile Weight %tile BMI (adults or teens Percentile wt/ht: only): Attach NCHS growth grids or Attach growth velocity charts Serum albumin: Tricep skinfold thickness: Additional justification: The information on this form is being treated as a physician prescription for medical care and services, and therefore, MUST be signed by CCS paneled physician. Name: License No.: Signature:_____Telephone No.:____ Address: Date: Submit to the GHPP program or CCS program

Examples of calorie dense enteral formulas are: Ensure, Ensure Plus, PediaSure, Sustacal, Sustacal with Fiber, Jevity, Scandishake or concentrated infant formulas that provide a caloric density greater than 20 calories per ounce.